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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yoav Kimchy

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MARTIN D. MOYNIHAN d/b/a PRTSI, INC.

P.O. BOX 16446

ARLINGTON, VA 22215

EXAMINER

MEHTA, PARIKHA SOLANKI

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,307	Applicant(s) KIMCHY ET AL.	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109, 113-142 and 144-164 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-109, 113-142 and 144-164 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/8/09, 4/26/09, 6/4/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1-109, 113-142 and 144-164 are objected to because of the following informalities:

Claim 1 recites, in line 5, “the position” without proper antecedent basis.

In claims 7, 4, 92 and 132, there should only be a single hyphenation between “collimation” and “deconvolution”.

Claims 19 and 67 recite “the body curvatures” and “the body” without sufficient antecedent basis.

In claim 21, it is unclear what is being set forth by merely “positions”.

Claim 22 fails to limit the inventive structure, as the radioactivity emitting source is not positively set forth as part of the claimed invention.

In line 3 of claim 23, “accelerometers” should be replaced with “accelerometer”.

In line 1 of claim 25, “and” should be removed.

In lines 25-30, it is unclear how the system can include a structural imaging “modality”, as “modality” refers to a class of objects, not the objects themselves.

In claim 32, the comma after “probe” should be removed.

Claim 39 recites “the radioactivity emitting source labeled with a radiopharmaceutical” without proper antecedent basis.

In claim 39, it is unclear how the recitation “particularly suited for” structurally limits the claimed invention.

In claims 40 and 88, it is unclear what structural limitation is set forth by “may thus be used”.

In claim 43, it is unclear what is being set forth by “data processing the scanning and the monitoring”, as scanning and monitoring are active steps, not data.

In claim 46, the comma following “motion” should be removed.

In claim 50, it is unclear how a collimator can construct an image.

Claim 63 recites “each position” and “the different attenuation” without proper antecedent basis.

In claims 54 and 106, it is unclear what is being set forth by “by the data processing”.

In claim 67, the comma following “pointer” should be removed.

In claim 68, it is unclear what is being set forth by “visually co-presenting”.

In claims 72-76, it is unclear what step is set forth by “performing a structural imaging modality”.

In claim 77, it is unclear how a method can include “a structural imaging modality”.

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In line 1 of claim 81, “a” should be removed.

In claim 82, it is unclear what is being set forth by “and of the”.

In claims 83-89, it is unclear how a method can include a surgical device.

Claim 90 recites "the position" and "the effect of wide-aperture" without proper antecedent basis.

In line 7 of claim 90, the comma following “source” should be removed.

Claim 105 recites “each position” and “the different attenuation” without sufficient antecedent basis.

In claim 123, it is unclear how the recitation “of a wide-aperture collimator” structurally limits the claimed invention.

In line 4 of claim 123, “being” should be removed.

Claim 123 recites “the position” without proper antecedent basis.

In claim 144, the commas following “the body” and “source” should be removed.

Claim 144 recites “the different attenuations” without proper antecedent basis.

In claim 148, the housing is set forth as comprising the probe; accordingly, the recitation of the probe being "mounted on said housing" appears to set forth that the probe is mounted on itself.

Claim 152 recites “the position of the probe” without proper antecedent basis.

In claim 159, it is unclear what is being set forth by “comprises the data processor being configured for tomographically [sic] reconstruct the image”.

Claim 162 recites “the data processor being configured to construct the image using a deconvolution algorithm” without proper antecedent basis.

Claims 163 and 164 recite "the time intervals" without proper antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1-6, 8, 9, 11-22, 24, 31-47, 50-52, 54-69, 71, 78-90, 93, 94, 96-109, 123-131, 133, 134, 136-142, 159, 160, 163 and 164, are rejected under 35 U.S.C. 102(e) as being anticipated by Weinberg (US Patent No. 6,628,984), hereinafter Weinberg ('984), of record.

Regarding claims 1-5, 19, 20, 22, 24 31, 34, 35, 40-47, 61-65, 67-69, 71, 78, 82, 88, 89, 103-109, 159, 160, 163 and 164, Weinberg ('984) discloses a system and method of using such system, wherein the system comprises a radioactive emission probe 156, a position tracking system 158 configured to track a position of the probe, and a data processor and computerized display 162/164 configured to receive data inputs from the tracking system to tomographically construct an image of a radioactivity emitting source using a plurality of radiation detections received from the probe and the position of the probe relative to the source (i.e. the distance between the probe and source) during said detections (Abstract, col., 2 lines 59-67). Weinberg ('984) discloses the probe as being configured for free-hand scanning, movement within a body lumen, and insertion via an endoscope (col. 10 lines 1-9). Weinberg ('984) also discloses an embodiment where the probe is configured for movement on a linkage system (Fig. 7).

Regarding claims 6, 8, 9, 50-52, 90, 93, 94, 123-131, 133, 134, Weinberg ('984) additionally discloses the data processor as receiving data inputs from the probe collimator, which inherently has an aperture/bore that can be subjectively deemed "wide" as claimed (col. 4 lines 17-23).

Regarding claims 11-15, 54-58, 96-100, 136-140, Weinberg ('984) discloses single and multiple collimator embodiments, including a grid collimator embodiment (col. 4 lines 17-26).

Regarding claims 16-18, 59, 60, 66, 81, 101, 102, 141, 142, Weinberg ('984) discloses multiple gamma radiation detectors (col. 10 lines 1-20, col. 11 lines 40-42).

Regarding claim 21, Weinberg ('984) creates an image of count rates as functions of positions (col. 9 lines 39-51).

Regarding claims 32, 33, 36-38, 79, 80, 83-85, 87, Weinberg ('984) discloses the probe as being mounted on a needle (col. 10 lines 29-38).

Regarding claims 39 and 86, Weinberg ('984) teaches simultaneous use of intracorporeal and extracorporeal probes (col. 10 lines 1-37).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7, 49, 92, 132, 161 and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg ('984) in view of Tournier (US Patent No. 6,680,750), hereinafter Tournier ('750), of record.

Weinberg ('984) substantially teaches the claimed invention as previously discussed for claims 1, 43, 90 and 123 but lacks means and steps for applying collimation-deconvolution algorithms. In the same field of endeavor, Tournier ('750) teaches a collimation deconvolution algorithm, and further teaches that it is useful for improving count rate (col. 3 lines 26-33). It would have been obvious to one of ordinary skill in the art to have modified Krakovitz ('423) and Daghighian ('336) to further include the collimation deconvolution algorithm of Tournier ('750), in view of the teachings of Tournier ('750).

7. Claims 10, 23, 48, 53, 70, 91 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg ('984).

Regarding claims 10, 53 and 95, Weinberg ('984) substantially teaches all features of the present invention as previously discussed for claims 1, 43, 95, but does not expressly teach a square collimator. Such changing of shape of a known element has previously been held as obvious and unpatentable over the prior art (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)); accordingly, the choice of a square collimator would have been obvious to a skilled artisan at the time of invention.

Regarding claims 23 and 70, Weinberg ('984) substantially teaches all features of the present invention as previously discussed for claims 1 and 43, but is silent as to the specific tracking system type used. Applicant has not disclosed that the claimed tracking systems solve a particular problem or present a patentable advantage over the prior art. Furthermore, accelerometers, potentiometers, ultrasonic

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trackers, RF trackers, EMF trackers and optical trackers are all known in the art. Accordingly, it would have been an obvious matter of design choice for a skilled artisan to have chosen any of the known tracking systems with the reference system and method, and to thereby yield the claimed invention.

Regarding claims 48 and 91, Weinberg ('984) teaches the invention as previously discussed for claims 43 and 90 but is silent as to the time intervals of the monitoring. Applicant has not disclosed that intervals of 100-200 milliseconds solve a particular problem or present a patentable advantage over the prior art. Accordingly, it would have been an obvious matter of design choice for a skilled artisan to have performed the method of Weinberg ('984) by performing the monitoring at intervals of 100-200 milliseconds.

8. Claims 25-30, 72-77 and 148-157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg ('984) in view of Krakovitz (US Patent No. 6,212,423), hereinafter Krakovitz ('423), of record.

Regarding claims 25-30, 72-77, 148-150, 152-155 and 157, Weinberg ('984) substantially teaches all features of the present invention as previously discussed for claim 1 but does not teach an additional imager. In the same field of endeavor, Krakovitz ('423) teaches a combined nuclear and ultrasonic imaging method and system including a probe sized for rectal insertion wherein the nuclear and ultrasonic images are displayed on a common system of coordinates (col. 6 lines 11-25 and 62-67). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Weinberg ('984) to include the ultrasonic imaging and integration means and steps of Krakovitz ('423) in order to provide a more comprehensive image of the radioactivity emitting source.

Regarding claims 151 and 156, although both Weinberg ('984) and Krakovitz ('423) are silent as to the viewing angle of the collimator, Applicant has not disclosed that angles of 81-280 degrees solve a particular problem or present a patentable advantage over the prior art; as such, it would have been an obvious matter of design choice for a skilled artisan to have used a collimator of such viewing angles with the system of Weinberg ('984) and Krakovitz ('423).

9. Claims 113-122 and 144-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovitz ('423) in view of Daghighian ('336) and Tournier ('750).

Regarding claims 144, 146 and 147, Krakovitz ('423) teaches a method and endoscopic system for simultaneous ultrasound imaging and radioactive emission detection, the system including a multiple collimators and a detector 721 (col. 5 lines 54-64), wherein detection of emission as taught by Krakovitz ('423) constitutes determination of "depth information from the surface of the body" as claimed.

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Krakovitz ('423) teaches a data processor configured to integrate the image and emission detection information in a three-dimensional image (col. 6 lines 11-25 and 62-67).

Krakovitz ('423) does not teach a position tracking system and method for the emission/imaging probe. In the same field of endeavor, Daghighian ('336) teaches a position tracking system and method for radioactive emission detecting probes, including means and steps for generating images of the area in which the distal tip of the probe is located within the patient's body (Abstract, col. 7 line 59 – col. 8 line 6). It would have been obvious to one of ordinary skill in the art to have modified Krakovitz ('423) to include the position tracking means and steps of Daghighian ('336), in order to allow for mapping and visualization of the probe position during the procedure.

Krakovitz ('423) and Daghighian ('336) lack steps for obtaining count rates for first and second photon energies. In the same field of endeavor, Tournier ('750) teaches a method of obtaining photon energy count rates via deconvolution methods in radiation emission detection (col. 4 lines 44-68), and further teaches that such method is advantageous for enabling a higher count rate than traditional cameras (col. 4 lines 31-34). It would have been obvious to one of ordinary skill in the art to have modified Krakovitz ('423) and Daghighian ('336) to include the count rate obtaining steps of Tournier ('750) and thereby achieve the claimed invention, in view of the teachings of Tournier ('750).

Regarding claim 145, although Krakovitz ('423), Daghighian ('336) and Tournier ('750) do not teach the specific equation recited therein, Applicant has not disclosed that such equation solves a particular problem or presents a patentable advantage over the prior art. Accordingly, it would have been nothing more than an obvious matter of design choice for a skilled artisan to have used such equation to derive at the position/depth information of Krakovitz ('423), Daghighian ('336) and Tournier ('750).

Regarding claims 113-122, Krakovitz ('423), Daghighian ('336) and Tournier ('750) are silent as to the type of collimator and pixels used for the probe. However, wide angle/bore, square, and grid collimators are known in the art, as are single- and multi-pixel detectors. Accordingly, it would have been obvious to one of ordinary skill in the art to have used any known collimator or detector with the probe of Krakovitz ('423) and Daghighian ('336), later modified by Tournier ('750), and thereby yield the claimed invention (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

10. Claim 158 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg ('984) in view of Krakovitz ('423), further in view of Daghighian (US Patent No. 6,510,336), hereinafter Daghighian ('336), of record.

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Weinberg ('984) and Krakovitz ('423) substantially teach the invention as previously discussed for claim 152, but do not expressly teach an optical imager. In the same field of endeavor, Daghighian ('336) teaches a combined nuclear and optical imaging probe. It would have been obvious to one of ordinary skill at the time of invention to have substituted the optical system of Daghighian ('336) for the ultrasonic system of Weinberg ('984) and Krakovitz ('423) and thereby yield the claimed invention, in order to facilitate optical analysis of the radioactive emitting source.

Response to Arguments

11. Applicant's arguments with respect to claims 1-109, 113-142 and 144-164 have been considered but are moot in view of the new ground(s) of rejection. Regarding claims 113-122, Examiner notes that a typographical error was made in the previous rejection; the claims should have been listed as rejected under Krakovitz, Daghighian and Tournier as set forth for claims 144-147, in view their dependence from claim 144. As Applicant did not argue the previous rejection of claims 113-122 under Krakovitz and Daghighian alone, Examiner assumed Applicant understood the Examiner's intention, and that this was merely a typographical error. Claims 144-147 and 113-122 remain rejected under Krakovitz, Daghighian and Tournier, as the position of the radioactive emitting source as detected by Krakovitz constitutes "depth position information" as claimed. The rejection of those claims is maintained and reiterated herein with additional explanation for clarity.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit
3737

/Parikha S Mehta/
Examiner, Art Unit 3737